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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,881	11/02/1999	MICHELINE MARKEY	15662-000900	1727

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/432,881	MARKEY ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,17,18,47-55,97,98,105-108,119,120 and 143-154* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,17,18,47-55,97,98,105-108,119,120 and 143-154* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **3/3/08** presents remarks and arguments to the office action mailed **10/01/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1-4, 17-18, 47-55, 97-98, 105-108, 119-120 and 143-154 are pending.

New *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 17-18, 47-48, 52-55, 97-98, 105-108, 119-120, 143-144, 148-149 and 152-154 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if

the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not provided a description of the structure of a representative number of compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

In other words, the Applicant has not described with sufficient clarity what the hydrophilic polymer that swells unrestricted dimensionally is. The specification fails to teach or adequately describe a representative number of species in this broad genus such that the common attributes or characteristics concisely identifying members of the genus are exemplified, and, because the claimed genus is so highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus. Also, regarding instant claims 54-55 reveals that they contain written description only of the content of a "water-soluble matrix" which is "coated" onto the surface of said solid matrix as defined in instant claim 52. Therefore, claims 54 and 55 provides no written description of the actual solid matrix (lines 2-3 of claim 1) regarding the hydrophilic polymer that swells unrestricted dimensionally.

Claims 1-4, 17-18, 47-48, 52-53, 97-98, 105-108, 119-120, 143-144, 148-149 and 152-154 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant amended claim by adding “hydrophilic” polymer in the instant claim does not have support. On page 15, lines 21-25 of the specification indicates “water swellable” as the polymer type in the invention. "hydrophilic” is a different characteristics to polymer from “water swellable”.

Claim Rejections - 35 USC § 102

Claims 1-4, 17-18 and 47-48,105-107 and 143-144 are rejected under 35 U.S.C. 102(b) as being anticipated by Kais et al., US Patent 5,516,524 (‘524)

Applicant argues that Kais et al. do not teach the limitation a solid matrix comprising a hydrophilic polymer that swell unrestricted dimensionally.

In response, These are characteristics of the polymer, for example it is well known in the art that methyl cellulose absorbs water , which expands in the stomach. See underlining evidence by Gao et al. J. Pharmaceutical Sciences 85(7) 1996.

Careful consideration has been given, however, found non-persuasive and the rejection is maintained and repeated as in the last office action of record.

The '524 patent discloses methods of treating constipation in human subjects by administering to said human a laxative composition (drug), dioctyl sulfoccinate (DSS), (fed mode agent) and the solid matrix-a bulk fiber methylcellulose (see abstract and also col. 7, lines 5-10), i.e., the solid matrix and, therefore, anticipates the claim since the specification at pages 6-7 discloses there is no definition of a solid matrix. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

The reference also discloses a dose of about 200 mg to 300 mg of sodium or calcium docusate (see abstract, col. 9-11, col. 13, lines 34-45, col. 14, lines 15-46) in current claims 14-18. The method steps of '524 are the same as the instant claims. Kais discloses administration of docusate metals to human patients, which is the same population as those instantly claimed. '524 discloses the use of docusate metals in the same dosing range as the instant claims. Relieving constipation induces at least a degree of fed mode within the scope of the instant claims. Since the disclosure of '524 meets all elements of the instant claims, this method also inherently anticipates the intended use of the instant claims. The properties, as recited in claims 2-6, 47-48, 105-107 and 143-144, will inherently be present in the compound. Thus the claims are anticipated as no patentable weight is given to use or function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 17-18, 47-55, 97-98, 105-108, 119-120, 1 and 143-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., US 6,120,803, taken with MacKenizie et al., Fundamental and Applied toxicology (of record) taken with Baichwal US 5,72,711 in view of Shell, US 5,582,837.

MacKenzie et al. disclose reduction of body weight/mass in individuals receiving the instant active agents (alkali and alkaline earth metal docusates) in claims 1 (b) and 17-18. (See abstract). Dioctyl sulfosuccinate is known in the art as docusate sodium). The instant claims 17-18 require administration of specific levels of active ingredient (see page 54, left column, second ¶, underlined section, and also at page 54, right hand col., under diet preparation, underlined). MacKenize discloses the active agent is present at 0.1, 0.5 or 1.0 %, calculated to be 1000 mg as the purity of the active metal docusate is 99.4% (see section Methods) which meets the limitation(s) of the claims.

Mckenzie, fails to teach the solid matrix comprising a hydrophilic polymer that swells unrestricted dimensionally.

Baichwal teach a controlled release formulation comprising ducusate sodium and hydrophilic polymers for absorption in the stomach. See col. 8, lines 17, and 30-35 as required by instant claims 1 and 152-154.

Shell teaches a sustained release oral drug dosage form for releasing in the stomach, that swells unrestricted dimensionally through inhibition of water from gastric fluid to increase the size of particles to promote gastric retention in fed mode induced patients. as required by instant claims 1-4. See col. 1, lines 62-65.

Wong et al. teach an active dosage form retained in the stomach for prolonged delivery, wherein the polymer matrix swells in the stomach (see abstract), wherein the compound is arginine (see col. 6, line 17), as in claims 1, 3 and 105, an alkaline, such as sodium salts (see col. 6, lines 22-26), as in the instant claims 1 and 105, wherein the composition is retained in the a solid matrix with said drug in a sustained manner (see col. 5, lines 28-42 and col. 6, lines 32-41), as in claims 2 and 106, wherein said mode inducing agent is separate from the solid matrix. The solid matrix-a polymer matrix (see col. 5, line 28-31) of claims 4 and 108. The size of the solid matrix is sufficiently large to promote retention. See col. 5, lines 55-67. As to claim 97 and 143, see the abstract where the first solid matrix is disclosed (see col. 2, lines 58-67 and col. 7, lines 17-25) and wherein the composition comprises a common single matrix (see col. 7, lines 17-19), as in claim 98.

With regard to claims 47-48, 52, and 143-144, osmotic pressure is disclosed in col. 6, lines 59-67. The matrix is of cellulose polymer, hydroxymethylcellulose; the

matrix is water soluble; and the water soluble matrix is cellulosic, sodium carboxymethylcellulose (see col. 5, lines 55-67), as in claims 49-55, 145-147, 149-151.

The instant claims differ in that the reference does not teach or suggest the fed inducing agent resides in a surface coating or layer on said solid matrix permitting substantially immediate release, as required by instant claims 3 and 107. However, the combination of teachings from the cited art especially that from Chen et al. and Wong teach, these agents are in a solid matrix (see col. 7, lines 17-33) wherein the fed mode inducing agent is a unitary compressed dispersion of a solid active agent in a gel forming erodible polymer and may contain a gastric emptying delaying agent that increases the retention time of the dosage form in the stomach. Since the gastric emptying delaying agent may be combined in the composition with the active agent (DSS) for local delivery to the environment of use, it may be coated on the dosage form to provide the desired physiological response (see col. 7, lines 28-32). Therefore, it resides in a surface coating and when in the stomach, the gastric fluid will cause the bonds of the polymer to break as swelling leads to the formation of very lose particles and prolonged retention of the solid matrix with a substantial release.

One of ordinary skill in the art would have been motivated to combine the above cited prior art and formulate a pharmaceutical composition that is used for promoting the fed mode of a patient in need thereof, as the compounds cited have been used either singularly or in combination to promote satiety.

Thus, at the time of filing this application, one of ordinary skill in the art would have found the instant pharmaceutical composition obvious over the combined

references. The references teach a fed mode inducing agent(s) for the claimed invention. The references are relied upon here because they have conveyed all of the claimed limitations for one of ordinary skill in the art. Accordingly, one of ordinary skill in the art would thus have been motivated to prepare said pharmaceutical composition with a reasonable expectation of success in doing so because the teachings are to a pharmaceutical agent with a prolonged release agent for gastric retention with a swellable dosage matrix. The polysoluble polymers are the same as those of the claimed invention. The skilled artisan would expect compounds of close structural similarities to possess similar properties.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
5/15/07

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614